



U.S. Navy Human Health Risk Assessment Guidance

Chapter 5 – Planning/Scoping

Table of Contents

5.0	Introduction	5-1
5.1	Purpose and Objectives	5-1
5.2	Team Identification	5-1
5.3	Regulator and Stakeholder Involvement	5-2
5.3.1	Regulator and Stakeholder Involvement	5-2
5.3.2	Planning Documents	5-3
5.4	Development of a Preliminary Conceptual Site Model	5-3
5.5	Data Requirements and Information Needs	5-4
5.5.1	Risk Assessment Data Needs	5-4
5.5.2	Site History	5-4
5.5.3	Site Data	5-4
5.5.4	Geographical Information Systems/Surveys/Base Maps	5-5
5.5.5	Physical Parameter Data	5-5
5.5.6	Fate and Transport Model Parameter Needs	5-6
5.5.7	Background Sampling	5-6
5.6	References	5-7

List of Tables

Table 5.1 – Examples of Modeling Data Needs	5-6
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List of Figures

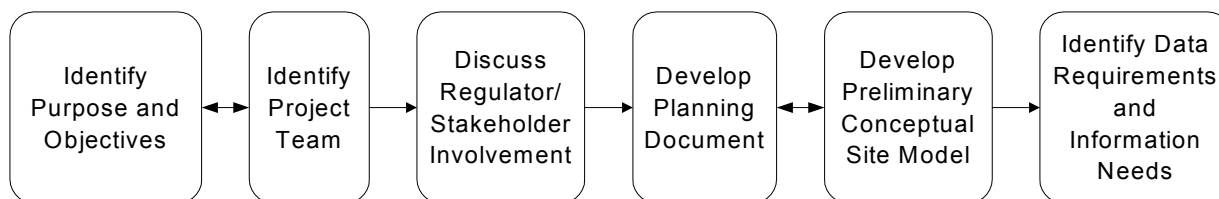
Figure 5.1 – Overview of the Planning/Scoping Process	5-1
Figure 5.2 – Example of a Conceptual Site Model	5-4



5.0 Introduction

Human Health Risk Assessments (HHRAs) can take on many different forms that require different types and amounts of information, depending on the needs of the site. This chapter discusses risk assessment related issues that Remedial Project Managers (RPMs) should consider when planning an environmental investigation. The general focus of this chapter is on risk assessments that are part of a Remedial Investigation/Feasibility Study (RI/FS) investigation, although much of the information is pertinent to other risk assessment situations as well. [Figure 5.1](#) presents an overview of the planning/scoping process.

Figure 5.1 – Overview of the Planning/Scoping Process



5.1 Purpose and Objectives

The purpose of the scoping process is to develop a “road map” that the project team can follow in order to achieve the overall project goals. Scoping also allows for the development of a comprehensive sampling and analysis plan that will satisfy the needs of each component of the project, while helping to ensure that time and budget constraints are met (USEPA, 1989). Planning for a risk assessment at the beginning of the process should be done in order to achieve the following objectives:

- ♦ minimize the cost of obtaining the information;
- ♦ maximize the amount of information that can be used in the risk assessment;
- ♦ identify all of the information that will be needed to complete the risk assessment; and
- ♦ identify stakeholders’ concerns about the risk assessment in order to address them, to the extent possible, during the RI/FS process.

Changing regulatory and political factors, stakeholder concerns, and results from different phases of the RI/FS process will result in different project risk assessment and data needs. As a result of these changes, project planning/scoping should occur throughout the project.

5.2 Team Identification

When developing a team for a project, it is important to consider the scope of the project and the activities that will most likely occur during the process. The complexity of the site is dictated by many factors such as the number of impacted media, the types of chemicals of potential concern (COPC), the extent of contamination, the number and types of currently-exposed populations, future land use considerations, and political considerations. The more complex a project, the more important that a multidisciplinary team (e.g., geologists, hydrogeologists, risk assessors, engineers, etc.) be assembled early in the process, to comprehensively address the technical issues posed by the site.

As a general rule it is wise to include risk assessors early in the process, in order to help develop the conceptual site model (CSM) and provide input concerning potentially exposed populations, exposure routes, and likely risks at the site. For example, if there are some preliminary data available, risk-based screening could be performed to get a sense of what media or chemicals are of potential concern. This



can greatly increase the effectiveness of the project team. In addition, risk assessors can identify data needs “up-front” and avoid key data gaps and costly re-sampling and analysis.

5.3 Regulator and Stakeholder Involvement

5.3.1 REGULATOR AND STAKEHOLDER INVOLVEMENT

Early in the process, RPMs should get to know who the stakeholders are, what their concerns are, how they perceive risk, and whom they trust. The following is a partial list of potential stakeholders:

- ♦ area residents;
- ♦ elected officials;
- ♦ civic organizations;
- ♦ health care providers;
- ♦ media;
- ♦ national, regional, state, tribal and local governmental organizations;
- ♦ environmental activists;
- ♦ business and industry;
- ♦ contractors;
- ♦ co-workers; and
- ♦ others.

The participation of stakeholders in a site remediation project depends on their concerns, attitudes, levels of interest, levels of involvement, histories, levels of knowledge, opinions, reasons for interest, and types of involvement (ATSDR, 2000). The likelihood of achieving a successful relationship with regulators and stakeholders increases with your knowledge of those with whom you are interacting.

Involving stakeholders early in the process allows them to voice their concerns, and potentially helps shape the remedial action process. In addition, frank and open discussions with stakeholders can often result in stakeholders feeling that they have ownership in the project. Stakeholders who have ownership in the project are more likely to look for ways to improve the process rather than trying to find ways to stop the process.

Inevitably, regulators and stakeholders have different concerns and ideas about how a risk assessment should be performed and how the information should be used in the decision-making process. The scoping process provides an excellent opportunity to interact with regulators and stakeholders in a constructive manner and to identify risk assessment related concerns and issues early in the process. This helps streamline the process by addressing stakeholders' concerns before the HHRA is initiated, rather than responding to comments after the document is completed. In addition, involving stakeholders may create a climate where coalitions can be developed and may change the dynamics of negotiations that occur with regulatory agencies. The United States Environmental Protection Agency (USEPA) is more likely to agree to a certain remedial alternative at a site if key stakeholder groups are supportive.



5.3.2 PLANNING DOCUMENTS

One mechanism for formally including regulators and stakeholders in the process is to develop a planning document (or protocol) that identifies the methodology that will be used to conduct the risk assessment. Risk assessment protocols vary significantly depending on the regulatory context, site complexity, and needs of the project team. Meetings should be conducted during the planning stages of the project to discuss and resolve stakeholders' and regulators' concerns regarding the approach to the HHRA presented in the protocol. Agreements regarding HHRA protocols should be documented in correspondence, comment and response records. Key elements of a HHRA protocol include the following:

- ♦ a conceptual site model that identifies the receptors of concern, exposure scenarios, and exposure pathways to be evaluated;
- ♦ how background data will be used in the risk assessment;
- ♦ the COPC selection process;
- ♦ the source of the toxicity criteria (cancer slope factors, reference doses) used in the risk assessment;
- ♦ the exposure scenarios, exposure assumptions, and algorithms used to quantify exposure; and
- ♦ the methodology that will be used to characterize the risk and the uncertainties.

The HHRA protocol should identify when a proposed approach varies significantly from that suggested by federal, regional, or state guidance, and provide an explanation as to why the variation is appropriate for the site under investigation. The RPM should be aware that USEPA and state requirements can differ significantly. Consequently, from a budget and schedule standpoint, it is prudent to discuss the risk assessment protocol with the stakeholders and regulators prior to the commencement of work.

If regulatory concurrence with a risk assessment protocol is desired, the RPM should emphasize to the reviewers that the involvement of a risk assessor from the regulatory community is important. At a minimum, Navy risk assessor(s) and risk assessor(s) from the regulatory agencies should be communicating with each other regarding risk assessment issues.

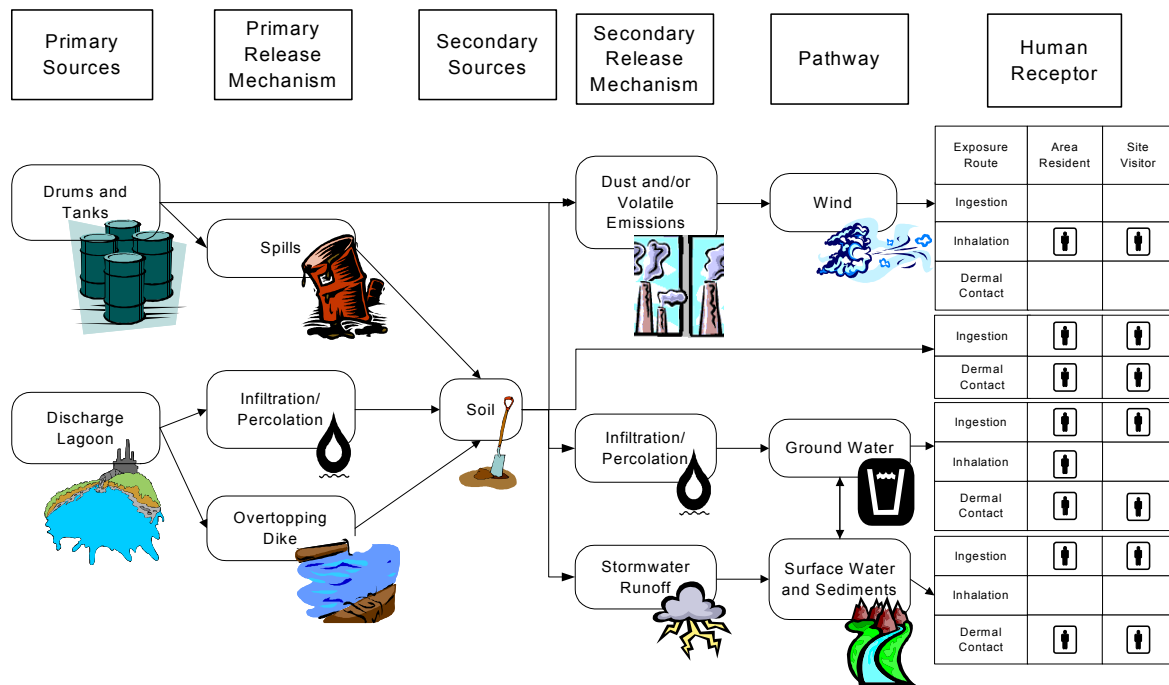
5.4 Development of a Preliminary Conceptual Site Model

A CSM generally includes a graphical depiction of how people come into contact with sources of contamination. [Figure 5.2](#) presents an example of a CSM. The CSM can be presented as a flow chart that depicts sources of contamination, migration pathways, exposed populations, and exposure routes. Alternatively, a CSM may consist of a picture of site conditions that conveys what is known or suspected, at a discrete point in time, about the sources, releases, release mechanisms, contaminant fate and transport, exposure pathways, potential receptors, and potential risks. The CSM can also be used as an effective tool in the scoping process to communicate site conditions to regulators and stakeholders.

The purpose of a CSM is to provide an understanding of the potential for exposure, under current and future land use, to chemicals at a site based on the source(s) of contamination, the release mechanism(s), the exposure pathway(s), and the receptor(s). Based on a CSM, a data collection strategy can be developed to prioritize field sampling activities and reduce uncertainty in risk characterization (e.g., contaminant release/transport mechanisms, spatial variability, presence of hot spots, etc.). A CSM may also provide sufficient information to allow for development of a strategy for early response actions to address exposure pathways that are considered complete and pose an imminent risk to public health (USDOE, 1997). The development of a CSM is critical to developing sampling and other work plans

because the process of creating the CSM results in a thorough compilation and evaluation of known information and identifies key questions that should be addressed during the site investigation.

Figure 5.2 – Example of a Conceptual Site Model



5.5 Data Requirements and Information Needs

5.5.1 RISK ASSESSMENT DATA NEEDS

The data needed for risk assessment purposes for a site will be identified through the CSM development and scoping process. The types of information that are needed for risk assessment purposes include information about general site history, site data, geographical information, physical parameters, fate and transport model inputs, and background data. Data are collected to characterize the site conditions, determine the nature of the wastes, assess the potential human health risks, and support treatability testing. Each of these components involves the collection, collation, and evaluation of information, which ultimately leads to specific risk management decisions.

5.5.2 SITE HISTORY

Historical data about a site provides crucial information that serves as the cornerstone of the scoping process. Historical information about the site's land use, such as industrial chemical processing and disposal practices, can focus the scoping process by providing key information about the probable nature and extent of contamination. Information about activity patterns at the site can be used to develop current exposure scenarios. Information about site processes, such as how a manufacturing process worked, provides insight about what chemicals were probably used and in what quantities.

5.5.3 SITE DATA

There are several types of data that are collected during site investigations that have associated uses in the risk assessment. Among these are the following.



- ♦ Analytical data are collected in order to identify chemicals of potential concern (COPCs) and their associated concentrations in potentially impacted media (e.g., soil, groundwater, surface water, etc.).
- ♦ Spatial distribution of COPCs information is used to identify complete exposure pathways, determine representative exposure point concentrations, and to help identify locations where people may come into contact with chemicals.
- ♦ Source characterization information is used to evaluate releases that are continual or have the potential to result in further contamination.
- ♦ Environmental setting data are used to characterize the environmental setting and to evaluate the fate, transport, and persistence of the contaminants. This may include chemical transformation information, such as degradation or attenuation rates.
- ♦ Fate and transport model inputs, such as particle size distributions, organic carbon content, and flow rates for streams are used to evaluate the extent to which a contaminant is transported and where it will be deposited.
- ♦ Background concentrations of chemicals (present due to natural or anthropogenic sources) for various media are used to identify COPC concentrations that are related to site activities.

While these types of data will be used in the risk assessment, it is also likely that other members of the project team will use them for different purposes, such as site characterization.

5.5.4 GEOGRAPHICAL INFORMATION SYSTEMS/SURVEYS/BASE MAPS

Geographical Information Systems (GIS) are important tools for performing risk assessments. This is especially the case for large complex sites where there are large quantities of data. At many complex sites, it is difficult to understand the spatial and chemical variability of COPCs and associated risks without a GIS system to help visualize the data. The following information will likely be needed for risk assessment purposes for complex sites where GIS is employed:

- ♦ spatial delineation of former land use activities, especially for land that was used for activities that resulted in potential contamination;
- ♦ spatial delineation of current land use activities;
- ♦ accurate sample location coordinates;
- ♦ spatial delineation of planned future land use activities (this is especially important for land that is going to be subdivided or used for different purposes); and
- ♦ the location of other geographic features such as creeks, lakes, etc.

These data should be maintained as part of the project data management system and typically are widely used by the project team to perform a variety of tasks such as calculating volume estimates, analyzing the analytical data for spatial trends, and communicating risks to others.

5.5.5 PHYSICAL PARAMETER DATA

In addition to analytical data, there is other site information that may also be obtained to better characterize potential exposure pathways. In some cases, plausible exposure pathways can be eliminated from further consideration if site-specific information is available that demonstrates that it is very unlikely that exposure will ever occur. For example, it is important to understand groundwater parameters such as turbidity and salinity. If groundwater at a site is brackish or if there are high amounts of suspended solids then it is unlikely that it will be used as a primary drinking water source. Depending



on the site, there may be other physical parameters that should be measured for the purposes of the risk assessment.

5.5.6 FATE AND TRANSPORT MODEL PARAMETER NEEDS

Fate and transport models are used to predict how chemicals will move in the environment (e.g., how chemicals in soil migrate to groundwater). Fate and transport models are often used in HHRAs to predict the concentration of chemicals in different media. Site-specific information is collected in order to increase the site-specificity of fate and transport models. Examples of site-specific information that may be useful for risk assessment purposes are presented in [Table 5.1](#).

Table 5.1 – Examples of Modeling Data Needs (USEPA, 1989)

Type of Modeling	Modeling Parameters
Source Characteristics	Geometry, physical/chemical conditions, emission rate, emission strength, geography.
Soil	Particle size, dry weight, pH, redox potential, mineral class, organic carbon and clay content, soil porosity.
Groundwater	Head measurements, hydraulic conductivity (pump and slug test results), saturated thickness of aquifer, hydraulic gradient, pH, redox potential, soil-water partitioning, turbidity, salinity.
Air	Prevailing wind direction, wind speeds, stability class, topography, depth of waste, contaminant concentration in soil and soil gas, fraction organic content of soils, site content of soils, percent vegetation, bulk density of soil, soil porosity.
Surface water	Hardness, pH, redox potential, dissolved oxygen, salinity, temperature, conductivity, total suspended solids, flow rates and depths for rivers/streams, estuary and embayment parameters such as tidal cycle, saltwater incursion extent, depth and area, lake parameters such as area, volume, depth, depth to thermocline.
Sediment	Particle size distribution, organic content, pH, benthic oxygen conditions, water content.
Biota	Dry weight, whole body, specific organ, and/or edible portion chemical concentrations, percent moisture, lipid content, size/age, life history stage.

Note: Many of the parameters may also be pertinent to other media.

Some of the information presented in [Table 5.1](#) may be useful in the risk assessment process because it provides data to support the exposure scenarios developed for the risk assessment.

5.5.7 BACKGROUND SAMPLING

A base- or site-specific background data set is often needed to distinguish site-related contamination from naturally-occurring or anthropogenic, background concentrations. This is particularly true for inorganics, but may also be significant for organics such as pesticides, polycyclic aromatic hydrocarbons (PAHs), and radionuclides. The size and quality of the site and background data-sets greatly affect the ability to determine whether chemical concentrations reflect background conditions or are elevated above background conditions.

Background samples are typically collected from each medium of concern at or near the hazardous waste site in areas not influenced by site contamination. Ideally, background samples would be collected from areas that could not have received contamination from the site, and that have the same basic characteristics as the media of concern at the site (USEPA, 1989).

Screening out chemicals based on site-specific background or reference-area concentrations is an important step in the identification of COPCs. The purpose of background screening is to focus the risk assessment on COPCs that are related to site activities and to eliminate COPCs that are present at



background or reference-area concentrations. Background is defined in the Navy Guidance as “either naturally occurring (nonanthropogenic) or anthropogenic (ambient), which are unrelated to Navy activities or operations (Naval Facilities Engineering Command September, 1998).”

The importance of background to site-specific, remedial decisions and the sophistication and limitations of the statistical tests that will be used to compare site and background concentrations should be considered during the planning stages of a project. Consequently, “up-front” planning to collect a representative data set is often necessary and may require the technical assistance of a statistician, geologist, and a risk assessment specialist.

5.6 References

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